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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,882	08/24/2001	Mark Plaia	5770.CD2C2	3541

7590 02/24/2006

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/938,882	Applicant(s) PLAIA ET AL.	
	Examiner Robert W. Amareld, Jr.	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/11/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 116-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 116-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 10/11/05. Accordingly, the following action has been made Non-Final.

Specification

The amendment filed 10/11/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: dissecting ring and prying device of claim 117 and 120.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 117, 118, 120, 128 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "including but not limited to" in claim 117 is a relative term which renders the claim indefinite. The term "including but not limited to" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A claim must be limiting in nature, this statement is essentially unlimited.

Claim 128 recites the limitation "occlusion reduction instrument" in claim 128. There is insufficient antecedent basis for this limitation in the claim as the parent claim 116 does not require an occlusion instrument.

Claims 118 and 120 are dependant on the affected claim 117.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 116-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiulli (US Pat# 4038985) in view of Wiktor (US Pat# 4886062). Chiulli discloses a means for engaging and removing plaque from the wall of a vessel (col. 3, lines 34-45) with cutting knurls and ridges(12), being a fixed diameter rotating blade device. However Chiulli does not disclose a lining carrier with means for releasibly holding and selectively deploying the lining. Wiktor teaches a hollow lining (1) being a stent and a lining carrier (5) being a balloon with a means for releasibly holding and selectively deploying the lining, the means for releasibly holding the lining being the balloon, and inflation of the

Art Unit: 3738

balloon for selectively deploying the lining as shown in Figures 4-6. The stent is radially expandable and is generally annularly extending and covering at least some of the wall and is fully capable of being folded to further reduce its diameter while still being in position on the releasably holding balloon, where balloons inherently function on expansion pressure. The device of Wiktor further includes a guide wire as an occlusion reduction instrument and a hollow tube as the catheter (9) as shown in Figure 3, where the tube has a solid wall, where the balloon is fully capable of being used for dilating the plaque prior to insertion of the plaque treating instrument and the stent has securing means, being the fully expanded form as shown in Figure 6. Wiktor's device is in the same field of endeavor or the analogous art of surgery for the purpose of occlusion repair. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of the inner lining and lining carrier, as taught by Wiktor, with the plaque treating device as per Chiulli, in order to repair an occlusion. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Furthermore, the author of the application in current prosecution indicates that the lining may be a sent on page 4, paragraph 0070.

Chiulli in view of Wiktor discloses the claimed invention except for the dissecting ring. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the knurled end of Chiulli with a manual manipulatable dissection ring, since applicant has not disclosed that such a design choice solves any stated problem or is anything more than one of numerous shapes, configurations or device choices, as is evident from the Markush type claim 117, a

Art Unit: 3738

person of ordinary skill in the art would find it obvious for the purpose of providing a cutting means. The use of cutting rings to remove occlusions is further evident by the surgical instrument of Cannon (US Pat# 2944552) In re Dailey and Eilers, 149 USPQ 47 (1966).

Terminal Disclaimer

The terminal disclaimer filed on 4/18/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6090135 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clark, Us Pat# 4030503 – embolectomy catheter; Alcond, Us Pat# 4674506- stent; Reger, US Pat# 5282484- artherectomy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert W Amareld, Jr.
Examiner
Art Unit 3738

RWA



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700